

[72] Inventor **Jerry D. Giesy**
Portland, Oreg.
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 [73] Assignees **James E. Tatooles**
Chicago,
fractional part interest to each;
George A. Raffel
Chicago, , fractional part interest to each;
Constantine J. Tatooles, Lincolnwood, Ill. ,
fractional part interest to each; Thomas J.
Fogarty, Portola Valley, Calif. , fractional
part interest to each; Jack M. Schneider,
Denver, Colo. , fractional part interest to
each

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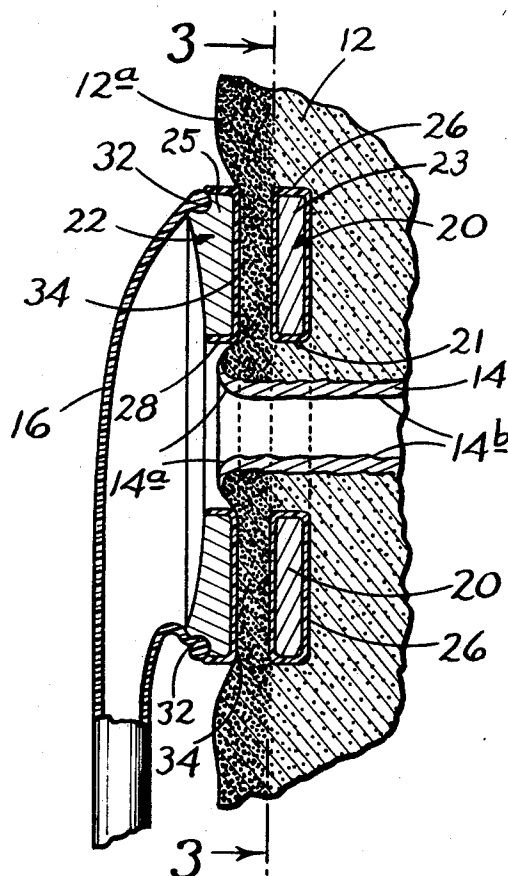
Primary Examiner—Charles F. Rosenbaum

Attorney—Wallenstein, Spangenberg, Hattis & Strampel

[54] **METHOD AND MEANS FOR ATTACHING A BODY APPENDAGE**
21 Claims, 3 Drawing Figs.

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 [50] Field of Search. 128/1, 283,
 346, 334, 348-351; 3/1; 32/2

ABSTRACT: Means attaching an appendage to an animal body comprising a stiff backing element embedded beneath the skin with a backing surface that faces outwardly, and an exteriorly carried complementing element held against the skin presenting a bearing surface that conforms to and is backed up by the backing surface of the embedded backing element.



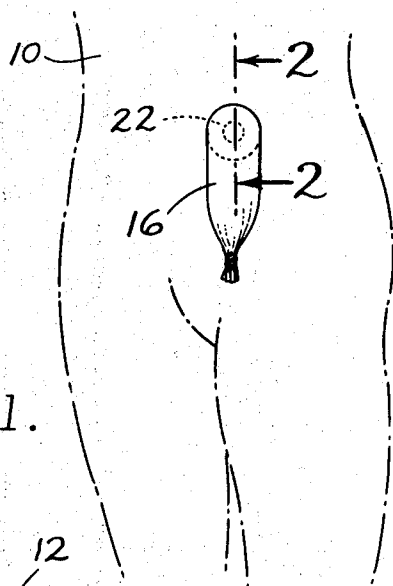


Fig. 1.

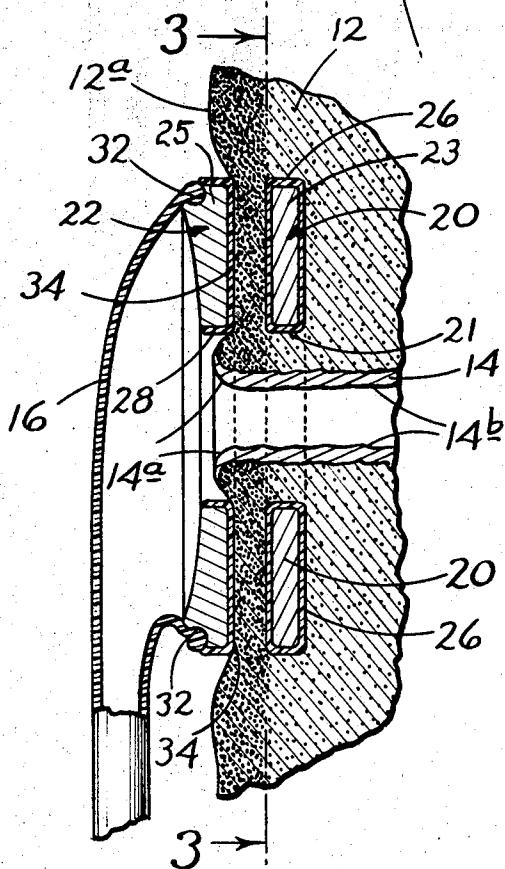


Fig. 2.

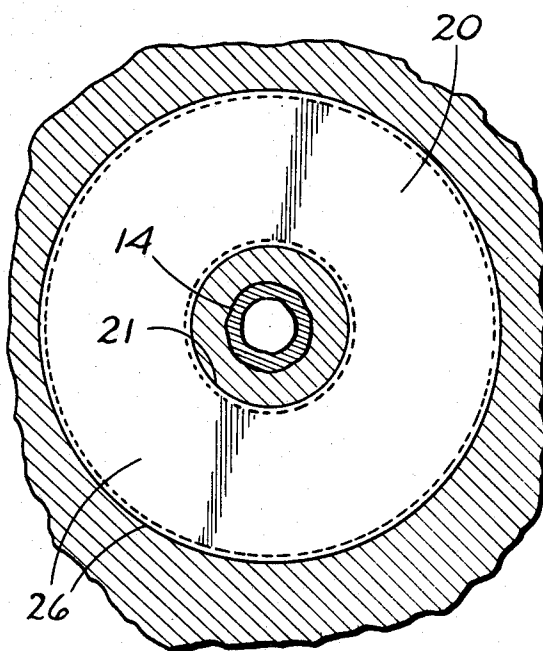


Fig. 3.

Jerry D. Giesy

BY

INVENTOR

Kelisch & Hartwell

Attys

METHOD AND MEANS FOR ATTACHING A BODY APPENDAGE

This invention relates to a method and means for attaching an appendage to the body of an animal.

Medical practice sometimes makes it necessary to attach an appendage to a patient to take care of functions that have been disrupted in the patient. Examples of such a need are found in patients who have undergone such operations as a colostomy, an ileostomy, or a ureterostomy, each of which leaves a patient with an opening extending through the abdominal wall through which waste matter may leave the body. In other appendage attachments, the discharge of waste matter is not involved. Whatever the type of appendage, it is usually a requirement that it be held firmly, and in a reliable manner, whereby the patient may be assured that the appendage will stay in place.

Particular problems are involved when the discharge of waste matter is a consideration. In this type of situation, the attachment is one which is constructed to receive the discharged waste material, and may be typically a bag or other receptacle. With such an appliance, provision ordinarily is made to permit the receptacle to be removed to enable it to be emptied.

In the past, difficulties have been experienced in obtaining a reliable union between the appendage and the skin because of the mobile, somewhat yielding characteristics of the usual expanse of skin, and because of the somewhat irregular contour of the skin as found in most regions of the body. As a consequence, when an appendage has been secured merely by using an adhesive to adhere it to the skin, there is a repeated working of the skin with movement of the patient, which tends to produce loosening and other undesirable effects. Many modes of attachment for appendages have tended to be less than satisfactory by reason of their being uncomfortable, bulky, and/or irritating to the skin. A particular problem is introduced in the case of appendages which receive waste matter, as in this instance a seal should ordinarily be provided between the appendage and the skin to prevent leakage, and the usual means producing a seal has been vulnerable to breaking of the seal.

Thus, a general object of this invention is to provide novel means for attaching an appendage to the skin of an animal, ordinarily a human, which permits a more reliable connection to be produced than generally possible in the past.

A related object is the provision of a novel method for attaching an appendage, such as a waste collection member against the skin of the animal.

According to the invention, a relatively stiff backing element is buried beneath the skin, which may be in the form of a plate having an evenly contoured face or backing surface positioned so that it faces outwardly on the patient. The region of skin that extends over the backing element is stiffened by the plate, and in a sense made less pliable or malleable. The appendage is then attached to this region of the skin through an exteriorly carried complementing element with a bearing surface that conforms to the backing surface of the backing element. The backing and bearing surfaces are opposite each other with the skin that extends over the backing element being, in a sense, sandwiched between the exteriorly carried complementing element and the backing element.

According to the invention, the appendage need not be strapped in place in its position. Instead, a union may be produced directly between the exteriorly carried element, the skin which is sandwiched between it, and the backing element, sufficient to hold the appendage in place with normal movements of the patient's body.

In a specific embodiment of the invention contemplated, where the appendage constitutes a receptacle intended to collect waste matter, the buried backing element and the exteriorly carried complementing element may comprise members such as annular members having passages extending through their centers. These passages enable the channeling through the elements of waste matter. A proper seal is produced inhibiting leakage between the exteriorly carried complementing element and the skin here such as against each other.

As also contemplated by a specific embodiment of the invention, and of particular importance where it is desired periodically to remove the appendage, the backing and exteriorly carried elements may be made, at least in part, of magnetic susceptible material, i.e., material which may be magnetized or attracted by a magnet. With at least one of the elements magnetized, a nonpermanent union of the exteriorly carried element with the skin is produced by magnetic attraction between the two elements.

As further contemplated by the specific embodiment of the invention, the backing element, which is buried or embedded beneath the skin, has some degree of mobility relative to bony or hard parts of the body behind the backing element. In this way, sudden jarring of the appendage is less likely to cause it loosening, as the shock of the jar is absorbed to a degree by the backing element displacing within the body.

These and other objects and advantages are attained by the invention, and the same is described below in conjunction with the accompanying drawings, wherein:

FIG. 1 is a view of the lower torso and upper leg portions of a human body, with an appendage attached to the body according to an embodiment of the invention;

FIG. 2 is an enlarged detail of the appendage attachment taken generally along the line 2-2 in FIG. 1; and

FIG. 3 is a view taken generally along the line 3-3 in FIG. 2.

Referring now to the drawings, in FIG. 1, at 10, there is indicated central portions of a human body with the front of the body generally facing the viewer. The body is that of a patient who has had a colostomy operation, in which the patient's rectum and a portion of his colon have been removed. In such an operation, ordinarily an end portion of the remaining colon is extended outwardly through an opening in the abdominal wall, to permit the discharge through such end portion of waste material. This is better illustrated in FIG. 2, where the skin and flesh comprising the abdominal wall are shown in cross section at 12, the epidermis or exterior layer of the skin is indicated generally at 12a, and the end of the colon which extends through the abdominal wall is indicated generally at 14. Ordinarily, the outer extremity 14a of the colon is sutured to the exterior of skin 12. Extremity 14a of the colon is referred to as a stoma, and acts in conjunction with passage 14b defined within the colon to provide for the discharge of waste from the body.

An appendage indicated generally at 16, in this instance a receptacle or bag for receiving waste material, is shown attached to the body adjacent where the colon opens up to the outer surface of the abdominal wall.

Describing now the means provided for attaching the receptacle in place, shown at 20 is a backing element which is embedded within the patient's skin. The particular backing element disclosed comprises an annular member having a central aperture 21 extending therethrough. The colon passes through the aperture 21 thus functioning to channel waste material through a midregion of the backing element. The element includes a core 23 made of a rigid or stiff material, and is shown encased in an envelope 26 of plastic or other closed-cell material, such material being nontoxic and substantially inert to body chemical reaction. The envelope of plastic, in addition to sealing off the core where such has toxic characteristics, also provides a cushioning effect inhibiting bruising or other damage to the body where such immediately surrounds element 20.

The left face of element 20 in FIG. 2 faces outwardly on the patient and constitutes a backing surface which shapes the layer of skin or epidermis extending over it to the configuration of the face. In this instance, the skin is shaped to extend as a substantially flat plane over the backing element. The malleable or pliable nature of the skin layer, where it extends directly over the element, is substantially reduced.

Cooperating with the buried backing element in forming a secure attachment between the appendage 16 and the skin is another annular element 22 provided with a central aperture indicated at 28. This element, referred to herein as an exteriorly

only carried complementing element, has a face or surface that faces to the right in FIG. 2. This face, therefore, conforms substantially to the backing surface presented by the buried backing element. The exteriorly carried element is directly opposite the buried element, and the layer of skin which extends over the backing element is sandwiched between the two elements.

Considering specifics of the exteriorly carried element 22, it may comprise a stiff or rigid plate 25 surfaced over its inner face with cushioning material 34 secured to plate 25 as by bonding it in place. The cushioning material is adapted to provide a cushion between the exteriorly carried element and the patient's epidermis, and also functions to provide a substantially fluidtight seal therebetween. The material further functions to increase friction, whereby the attachment when positioned against the epidermis tends to be held from sliding out of place. The material marketed as "SpenceGel" by Stryker Corporation of Michigan, constitutes a good material for covering the face of plate 25.

Plate 25 has an annular groove 32 extending around its perimeter, and this groove is employed in attaching the receptacle or bag 16 to the plate. Thus, the bag may be provided around its mouth with a conforming bead, which may be stretched slightly to be snapped into place in the groove. With element 22 against the skin opposite element 20, aperture 28 registers with outer extremity 14a of the colon and defines part of a passage through which waste material is channeled into bag 16.

As contemplated by the invention, a union is formed between the inner face of element 22 and the skin whereby the appendage is held in place with a seal produced where element 22 engages the skin. This union of the element to the skin may be produced with an adhesive, which serves directly to adhere the skin and element together. By reason of the buried backing element 20, the appendage will stay in place in a far more lasting manner than were the attachment to be adhered to the skin without any attempt to shape the skin and reduce its malleability, as contemplated.

In the particular embodiment of the invention illustrated, the union of the externally carried element with the skin is a nonpermanent one, produced by magnetic attraction between the buried backing element and externally carried element 22. With this type of organization, receptacle 16 is easily removed for cleaning purposes, and then replaced with a tight seal then being produced, without the necessity of preparing an adhesive bond each time the appendage is returned.

Thus, and more specifically, in the particular embodiment of the invention disclosed, element 20 comprises a core 23 of magnetic-susceptible material. Element 22 comprises a plate 25 of magnetic-susceptible material. The term "magnetic-susceptible" denotes that they are composed of materials which may be magnetized or attracted by a magnet. While both elements may comprise magnetized pieces with proper polarity, to produce the strongest attraction between the two elements, only one element need be magnetized, in most instances. In the usual case where only one element is magnetized, it is preferable to have element 20 the permanent magnet, rather than element 22, as the permanent magnet may have more mass than the externally carried element. Such mass is more reliably supported by having it embedded within the skin. With elements 20, 22 being attracted to each other by magnetic force, there is some compression of the skin layer where it is sandwiched between the two elements, which contributes to a tight seal and resistance to slipping by the externally carried element.

It is a relatively simple matter to prepare a patient for the attachment of an appendage using the apparatus described. During the performance of the colostomy operation, or at some subsequent period, the backing element is embedded within the patient's skin between the epidermis and the underlying fascia. The backing element ordinarily is embedded at a depth within the skin whereby a continuing blood supply is permitted to the superficial layers of the skin. The element is

placed with its central aperture receiving the colon which extends through it. With the backing element in place, the appendage is attached by positioning it opposite the buried backing element.

With an appendage attached as contemplated, bulky straps and other devices may be dispensed with, irritation of the skin is minimal, and the patient's confidence is greatly increased since a form of attachment has been produced which may be relied upon. The shape and positioning of the magnetic or magnetized elements 20 and 22 produce balanced magnetic forces which avoids the tilting of one element with respect to the other which could cause irritation or damage to the skin.

While there has been described a particular embodiment of the invention, obviously variations and changes are possible without departing from the invention. Accordingly, it is desired to cover all such modifications and variations as would be apparent to one skilled in the art and that come within the scope of the appended claims.

I claim:

1. Method of attaching an appendage against the outer skin of an animal comprising placing a backing element within the soft parts of the animal's body adjacent a region of its skin with a backing surface of the backing element facing outwardly on the animal, said backing element being stiff relative to said soft parts including said skin and is unanchored to any rigid part of the body so the backing element is free to shift laterally with said skin, providing an appendage including a complementing element with an exposed bearing surface which is adapted to confront the backing surface of the backing element, and affixing the appendage on the animal with the bearing surface of said complementing element snugly against the animal's skin and opposite and facing the backing surface of the backing element to leave the skin where it extends in front of the backing element sandwiched between the complementing element and the backing element, the said complementing element being unattached to said backing element so it is free to shift laterally with respect thereto.

2. The method of claim 1, wherein said appendage is a material receiving means for receiving materials passing through a passageway of the animal to the outside thereof, said backing element comprises an annulus surrounding said passage so the passageway channels such waste matter through the annulus to said material receiving means.

3. The method of claim 2, wherein said material receiving means is a self-contained receptacle and said complementing element also is an annulus, the complementing element surrounds said passageway so said material in the animal is channeled through the complementing element and the annular complementing element forms an annular seal on said skin for said receptacle surrounding the terminals of said passageway so said material will not leak to the exterior of said receptacle.

4. The method of claim 1 which further comprises drawing the complementing element and the backing element together by magnetic attraction.

5. The method of claim 1, wherein at least one of said elements presents a cushion forming layer facing said skin.

6. Means attaching an appendage to an animal body comprising, in operative position, a backing element positioned in the soft parts of the animal's body adjacent a region of its outside epidermis so as to be free to shift in position laterally with the epidermis, said backing element having a backing surface which faces outwardly on the animal, and a complementing element forming part of said appendage and having a bearing surface which generally conforms to the backing surface of the backing element, said bearing surface including means for securing the same to the outside of said epidermis where it faces and is opposite the backing surface of the backing element so said region of the animal's epidermis is sandwiched between the complementing element and the backing element, said backing and complementing elements being unconnected so they can shift laterally with respect to one another.

7. The means claimed in claim 6, wherein said backing element includes a body of material which is stiff relative to said epidermis to provide a stiff backing surface, and at least one of said elements has on the side thereof facing said epidermis a relatively thin layer of cushion forming material, and said elements include means for forcing said elements together to hold the complementing element and the appendage of which it forms a part in position on said epidermis despite some limited relative lateral shifting movement between said elements.

8. The means claimed in claim 6, wherein said backing element has an aperture which receives a duct in the animal's body channeling material to the surface of its body, said exteriorly carried complementing element forms part of a receptacle for receiving said material and has an aperture opening onto said duct, and the exteriorly carried complementing element is sealed to the epidermis of the animal around said duct to prevent leakage of said material from said receptacle.

9. The means claimed in claim 6, wherein said backing element and exteriorly carried complementing element are each at least partly comprised of a magnetic-susceptible material, at least one of said elements is a magnet, and the exteriorly carried element is held against the epidermis by magnetic attraction between the two elements.

10. The means claimed in claim 6, wherein said exteriorly carried complementing element includes a cushion and said bearing surface is presented by said cushion.

11. The means claimed in claim 6, wherein at least a portion of said backing element is stiff relative to said epidermis so it presents a stiff backing surface for said epidermis.

12. Means attaching an appendage to an animal body comprising, in operative position, a backing element positioned in the soft parts of the animal's body adjacent a region of its outside epidermis, said backing element having a backing surface which faces outwardly on the animal, and an exteriorly carried complementing element in the appendage having a bearing surface which is substantially complementary to and confronts the backing surface of the backing element, said bearing surface facing and being opposite the backing surface of the backing element whereby said region of the animal's epidermis is sandwiched between the complementing element and the buried backing element, and said backing element and exteriorly carried complementing element are each at least partly comprised of a magnetic-susceptible material, at least one of said elements is a magnet, and the exteriorly carried complementing element being held against the epidermis by magnetic attraction between the two elements.

13. The means claimed in claim 12 which further includes a receptacle to receive material passing to the outside of the animal's body through a passageway extending thereto, and sealing means forming a seal between the exteriorly carried complementing element and the epidermis of the animal to prevent leakage of material from said receptacle, each of said elements comprises a member with an opening through which said passageway extends or terminates so said material passes to said receptacle held on the skin by said magnetic attraction.

14. The means claimed in claim 12, wherein at least a portion of said backing element is stiff relative to said epidermis so it presents a stiff backing surface for said epidermis.

15. The means of claim 12, wherein said backing and complementing elements are laterally shiftable with respect to

each other and are of a size and shape and are positioned to provide balanced forces keeping the same in parallel relation.

16. The means claimed in claim 14 wherein at least one of said elements has on the face thereof facing said epidermis a layer of cushion forming material.

17. The means claimed in claim 16 wherein both of said elements present confronting backing and bearing surfaces which are stiff relative to said epidermis and have applied to said surfaces a relatively thin layer of cushion forming material.

18. The means of claim 13, wherein said passageway is a waste discharging duct opening into a flat or flattened portion of said epidermis, and said complementing and backing elements are flat members extending generally parallel to the flat or flattened portion of said epidermis.

19. Means attaching an appendage to an animal body comprising, in operative position, a backing element positioned in the soft parts of the animal's body, said backing element having a backing surface which faces outwardly on the animal, and an exteriorly carried complementing element in the appendage having a bearing surface which is substantially complementary to and confronts the backing surface of the backing element, said backing and complementing elements being unconnected so they can shift laterally with respect to one another, said bearing surface of said complementing element facing and being opposite the backing surface of the backing element whereby said region of the animal's epidermis is sandwiched between the complementing element and the buried backing element, and at least said backing element including a body of material which is stiff relative to said epidermis to provide a stiff backing surface, and at least one of said elements presenting on the side thereof facing said epidermis a layer of cushion material, and said elements include means for forcing said elements together to hold the complementing element in position on said epidermis.

20. A method of attaching a material receiving appendage to the outer skin of an animal to receive material passing to the outside of the animal's body through a passageway extending thereto, said method comprising embedding a backing element surrounding said passageway in the soft parts of the animal's body adjacent a region of its skin so the backing element is isolated from the exterior of the skin, the backing element having a backing surface facing outwardly on the animal, providing said material receiving means with a complementing element having an exposed bearing surface which is adapted to confront the backing surface of the backing element, and placing the appendage on the animal with the bearing surface of said complementing element snugly against the animal's skin and confronting the backing surface of the backing element to leave the skin where it extends in front of the backing element sandwiched between the complementing element and the backing element.

21. The method of claim 20 wherein said material receiving means is a self-contained receptacle and said complementing element also is an annulus, the complementing element surrounding said passageway so said material in the animal is channeled through the complementing element, and the annulus complementing element forming an annular seal on said skin for said receptacle surrounding the terminals of said passageway so said material will not leak to the exterior of said receptacle.